

Atty. Dkt. No. 036222-0212



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Albert R. Deisseroth and Lixin Zhang  
 Title: ADENOVIRAL VECTOR VACCINE  
 Appl. No.: 10/534,605  
 Filing Date: 05/11/2005  
 Examiner:  
 Art Unit:

CERTIFICATE OF MAILING	
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July 19, 2005 (Date of Deposit)	

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop Amendment-IDS  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

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**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

Date July 19, 2005  
FOLEY & LARDNER LLP  
Customer Number: 30542  
Telephone: (858) 847-6722  
Facsimile: (858) 792-6773

By Barry Wilson  
Barry S. Wilson  
Attorney for Applicant  
Registration No. 39,431

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<b>Substitute for form 1449B/PTO</b> <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b> <i>AUG 04 2005</i> <i>(use as many sheets as necessary)</i> <i>Sheet _____ of _____</i> <b>1</b> <b>of</b> <b>9</b>		<b>Complete if Known</b>	
		Application Number	10/534,605
		Filing Date	May 11, 2005
		First Named Inventor	Albert B. Deisseroth
		Group Art Unit	
		Examiner Name	
		Attorney Docket Number	036222-0212

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
A1	2003/0176377	Xiang, et al.		09-18-2003	
A2	4,161,519	Talwar		07-17-1979	
A3	4,608,251	Mia		08-26-1986	
A4	5,658,785	Johnson, Phillip		08/19/1997	
A5	5,849,522	Fleckenstein, et al.		12/15/1998	
A6	5,849,876	Linsley, et al.		12/15/1998	
A7	5,874,085	Mond, et al.		02/23/1999	
A8	5,928,913	Efstathiou, et al.		07/27/1999	
A9	5,962,406	Armitage, et al.		10/05/1999	
A10	6,017,527	Maraskovsky, et al.		01/25/2000	
A11	6,040,174	Imler, et al.		03/21/2000	
A12	6,087,329	Armitage, et al.		07/11/2000	
A13	6,110,744	Fang, et al.		08/29/2000	
A14	6,133,029	Gruber, et al.		10/17/2000	
A15	6,147,055	Hobart, et al.		11/14/2000	
A16	6,218,140	Fleckenstein, et al.		04/17/2001	
A17	6,224,870	Segal, Andrew		05/01/2001	
A18	6,287,557	Bournsnel, et al.		09/11/2001	
A19	6,290,972	Armitage, et al.		09/18/2001	
A20	6,294,654	Bogen, et al.		09/25/2001	
A21	6,440,944	Bruder, et al.		08/27/2002	
A22	6,482,407	Soo Hoo, William		11/19/2002	
A23	6,497,876	Maraskovsky, et al.		12/24/2002	
A24	6,500,641	Chen, et al.		12/31/2002	
A25	6,566,128	Graham, et al.		05/20/2003	
A26	6,794,188	Barsov		09-21-2004	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY
		Office <sup>3</sup>	Number <sup>4</sup>		
A27	WO 2004/044176			Deisseroth et al.	05-27-2004
A28	WO 96/11279			The Government of the United States of America	04-18-1996
A29	WO 98/17799			The Trustees of the University of Pennsylvania	04-30-1998

Examiner Signature	/Phillip Gambel/	Date Considered	07/06/2010
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			Filing Date	May 11, 2005	
			First Named Inventor	Albert B. Deisseroth	
			Group Art Unit		
(use as many sheets as necessary)			Examiner Name		
Sheet	2	of	9	Attorney Docket Number	036222-0212

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A30	ALLISON and Byars, "Immunological Adjuvants and their mode of action." (in <u>Vaccines: New Approaches to Immunological Problems</u> , R. Ellis ed., Chapter 19), pp. 431-449.	
	A31	ANDRIANIFAHANANA, et al., "Mucin (MUC) Gene Expression in Human Pancreatic Adenocarcinoma and Chronic Pancreatitis: A Potential Role of MUC4 as a Tumor Marker of Diagnostic Significance," <i>Clin Cancer Res.</i> 7:4033-4040 (2001)	
	A32	ARAI, et al., "Design of the linkers which effectively separate domains of a bifunctional fusion protein," <i>Protein Engineering</i> , 14(8):529-532 (2001)	
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	A35	Bell et al., "Dendritic cells." (in <u>Advances in Immunology</u> , edited by Frank J. Dixon, Academic Press, Volume 72), 255-324, 1999.	
	A36	Broder et al., Recombinant adenovirus-transduced dendritic cell immunization in a murine model of central nervous system tumor <i>Neurosurg Focus</i> 9:1-8, 2000.	
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	A38	CHEN, et al., Linkage of CD40L to a self-tumor antigen enhances the antitumor immune responses of dendritic cell-based treatment. <i>Cancer Immunology Immunother.</i> 51(6):341-348, 2002	
	A39	CHOUDHURY, et al., Dendritic cells derived in vitro from acute myelogenous leukemia cells stimulate antigenic, antileukemic T-cell responses. <i>Blood</i> ; 93(3) : 780-786, 1999.	
	A40	Crook et al., Continued expression of HPV-16 E7 protein is required for maintenance of the transformed phenotype of cells co-transformed by HPV-16 plus EJ-ras. <i>EMBO J.</i> 8: 513-519, 1989.	
	A41	DAKAPPAGARI et al.; "Chimeric multi-human epidermal growth factor receptor-2 B cell epitope peptide vaccine mediates superior antitumor responses," <i>J Immuno.</i> 170(8):4242-4253 (2003)	

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	A42	Dhadakar, et al. Rapid generation of broad T-cell immunity in humans after a single injection of mature dendritic cells. <i>J Clin Invest.</i> 104: 173-180, 1999.	
	A43	ECK and TURKA, Generation of protective immunity against an immunogenic carcinoma requires CD40/CD40L and B7/CD28 interactions but not CD4+T cells. <i>Cancer Immunology Immunother.</i> 48:336-341, 1999.	
	A44	ENGELMANN, et al., Identification and topology of variant sequences within individual repeat domains of the human epithelial tumor mucin MUC1. <i>J. Biol. Chem.</i> 276:27764-27769 , 2001.	
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	A49	GARCON et al., "Universal vaccine carrier. Liposomes that provide T-dependent help to weak antigens," <i>J. Immunol.</i> 146:3697 (1991)	
	A50	GENDLER S.J. et al, "Molecular cloning and expression of human tumor-associated polymorphic epithelial mucin," <i>J. Biol. Chem.</i> 265:15286-15293 (1990)	
	A51	GONG, et al., "Selection and characterization of MUC1-specific CD8+ cells from MUC1 transgenic mice immunized with dendritic-carcinoma fusion cells." <i>Immunology</i> , 101:316-324 (2000)	
	A52	GREENLEE, et al., "Cancer statistics, 2000," <i>Cancer J.</i> 50:7-33 (2000)	
	A53	Gunzer et al., Dendritic cells and tumor immunity. <i>Semin Immunol</i> 13:291-302, 2001.	
	A54	GUY, et al. "Expression of the neu protooncogene in the mammary epithelium of transgenic mice induces metastatic disease," <i>Proc. Natl. Acad. Sci. USA</i> 89:10578-10582 (1992)	

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Sheet	4	of	9	Attorney Docket Number	036222-0212

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	A55	HOLLINGSWORTH, et al., "Expression of MUC1, MUC2, MUC3, and MUC4 mucin mRNA in human pancreatic and intestinal tumor cell lines," <i>Int J Cancer</i> 57:198-203 (1994)	
	A56	Hsu et al. Vaccination of patients with B-cell lymphoma using autologous antigen-pulsed dendritic cells. <i>Nat Med.</i> 2: 52-58, 1996.	
	A57	JEANNON, et al. "Altered MUC1 and MUC2 glycoprotein expression in laryngeal cancer," <i>Otolaryngol/ Head Neck Surg.</i> 124:199-202 (2001)	
	A58	JOHNSON, et al., "Characterization of a Nontoxic Monophosphoryl Lipid A," <i>Rev. Infect. Dis.</i> 9:S512 (1987)	
	A59	KANEDA, "New Vector Innovation for Drug Delivery: Development of Fusogenic Non- Viral Particles," <i>Curr Drug Targets</i> 4(8):599-602 (2003)	
	A60	KIM, et al., "Aberrant expression of MUC5AC and MUC6 gastric mucins and sialyl Tn antigen in intraepithelial neoplasms of the pancreas," <i>Gastroenterology</i> 123:1052-1060 (2002)	
	A61	KONTANI, et al., "Modulation of MUC1 mucin as an escape mechanism of breast cancer cells from autologous cytotoxic T-lymphocytes," <i>Br. J. Cancer</i> 84:1258-1264 (2001)	
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	A63	Lamikanra et al., Regression of established human papillomavirus type 16 (HPV-16) immortalized tumors <i>in vivo</i> by vaccinia viruses expressing different forms of HPV-16 E7 correlates with enhanced CD8(+) T-cell responses that home to the tumor site. <i>J Virol.</i> 75: 9654-9664, 2001.	
	A64	Larsson et al., A recombinant vaccinia virus based ELISPOT assay detects high frequencies of Pol-specific CD8 T cells in HIV-1-positive individuals. <i>AIDS</i> 13:767-777, 1999.	
	A65	Liu et al., Codon Modified Human Papillomavirus Type 16 E7 DNA Vaccine Enhances Cytotoxic T-Lymphocyte Induction and Anti-tumor Activity. <i>Virology</i> 15: 301-343, 2002.	

Examiner Signature	/Phillip Gambel/	Date Considered	07/06/2010
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	A66	Luft et al., IFN-alpha enhances CD40 ligand-mediated activation of immature monocyte-derived dendritic cells. <i>Int Immunol</i> 14:367-380, 2002		
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	A68	MOREIN, et al., "Iscom, a novel structure for antigenic presentation of membrane proteins from enveloped viruses," <i>Nature</i> 308:457 (1984)		
	A69	MULLER, et al., "Single-step induction of mammary adenocarcinoma in transgenic mice bearing the activated c-neu oncogene," <i>Cell</i> 54(1):105-115 (1988)		
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	A71	Nestle et al. Vaccination of melanoma patients with peptide- or tumor lysate-pulsed dendritic cells. <i>Nat Med</i> . 4: 328-332, 1998.		
	A72	NGUYEN, et al., "Membrane-bound (MUC1) and secretory (MUC2, MUC3, and MUC4) mucin gene expression in human lung cancer," <i>Tumor Biol</i> . 17(3):176-192 (1996)		

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	A73	O'HAGAN, et al., "Biodegradable microparticles as controlled release antigen delivery systems," <i>Immunology</i> 73:239-242 (1991)	
	A74	Paglia P, et al. Murine dendritic cells loaded <i>in vitro</i> with soluble protein prime cytotoxic T lymphocytes against tumor antigen <i>In vivo</i> (see comments). <i>J Exp Med</i> 183: 317-322, 1996.	
	A75	Palucka and Banchereau, Dendritic cells: A link between innate and adaptive immunity. <i>J Clin Immunol</i> . 19:12-25, 1999.	
	A76	REDMOND, et al., "Rotavirus particles function as immunological carriers for the delivery of peptides from infectious agents and endogenous proteins," <i>Mol. Immunol.</i> 28:269 (1991)	
	A77	REGIMBALD, et al., "The breast mucin MUC1 as a novel adhesion ligand for endothelial intercellular adhesion molecule 1 in breast cancer," <i>Cancer Res.</i> 56:4244-4249 (1996)	
	A78	REN, et al., "Protein Kinase C Regulates Function of the DF3/MUC1 Carcinoma Antigen in -Catenin Signaling"; <i>J. Biol. Chem.</i> 277:17616-17622 (2002)	
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	A81	Rininsland et al., Granzyme B ELISPOT assay for ex vivo measurements of T cell immunity. J Immunol Methods 240:143-155, 2000.	
	A82	ROWSE, et al., "Tolerance and immunity to MUC1 in a human MUC1 transgenic murine model," Cancer Res. 58:315 (1998)	
	A83	Rudolf et al., Human dendritic cells are activated by chimeric human papillomavirus type-16 virus-like particles and induce epitope-specific human T cell responses <i>in vitro</i> . J Immunol. 166: 5917-5924, 2001	
	A84	Shortman K, and Caux C. Dendritic cell development: multiple pathways to nature's adjuvants Stem Cells 15:409-419, 1997	
	A85	Skov et al., IL-2 and IL-15 regulate CD154 expression on activated CD4 T cells J Immunol. 164:3500-3505, 2000.	
	A86	Steinbrink et al., CD4(+) and CD8(+) anergic T cells induced by interleukin-10-treated human dendritic cells display antigen-specific suppressor activity. Blood 99: 2468-2476, 2002.	
	A87	TANG et al., "Multistep process through which adenoviral vector vaccine overcomes anergy to tumor-associated antigens." Blood, 104:2704-2713, 2004.	
	A88	Timmerman and Levy, Dendritic cell vaccines for cancer immunotherapy. Annual Rev Med. 50: 507-529, 1999.	

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	A89	THOMAS, et al., "Non-viral gene therapy: polycation-mediated DNA delivery," <i>Appl Microbial Biotechnol</i> 62(1):27-34 (2003)	
	A90	WANG, et al., "Essential roles of tumor-derived helper T cell epitopes for an effective peptide-based tumor vaccine," <i>Cancer Immun.</i> 3:16 (2003)	
	A91	XIANG, et al., "A dual-function DNA vaccine encoding carcinoembryonic antigen and CD40 ligand trimer induces T cell-mediated protective immunity against colon cancer in carcinoembryonic antigen-transgenic mice," <i>The Journal of Immunology</i> , 167:4560-4565 (2001)	
	A92	YAMAMOTO M., et al., "Interaction of the DF3/MUC1 Breast Carcinoma-associated Antigen and -Catenin in Cell Adhesion," <i>J. Biol. Chem.</i> 272:12492-12494 (1997)	
	A93	YANAGI, et al., "Immuno-gene therapy with adenoviruses expressing fms-like tyrosine kinase 3 ligand and CD40 ligand for mouse hepatoma cells in vivo," <i>International Journal of Oncology</i> 22:345-351 (2003)	
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	A96	ZHENG et al., "Induction of antitumor immunity via intratumoral tetra-costimulator protein transfer," <i>Cancer Research</i> 61:8127-8134 (2001)	

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			<b>Filing Date</b>	May 11, 2005
			<b>First Named Inventor</b>	Albert B. Deisseroth
			<b>Group Art Unit</b>	
			<b>Examiner Name</b>	
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	A97	Zitvogel L, et al. Therapy of murine tumors with tumor peptide-pulsed dendritic cells: dependence on T cells, B7 co-stimulation, and T helper cell 1-associated cytokines. <i>J Exp Med.</i> 183: 87-97, 1996.	
	A98	ZRIHAN-LICHT S., et al., "Tyrosine phosphorylation of the MUC1 breast cancer membrane proteins. Cytokine receptor-like molecules," <i>FEBS Lett.</i> 356:130-136 (1994)	
	A99	Zwaveling et al., Established human papillomavirus type 16-expressing tumors are effectively eradicated following vaccination with long peptides. <i>J Immunol.</i> 169:350-358, 2002.	

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